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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,494	09/17/2001	James G. Castillo	3863.015	8042

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[REDACTED] EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	3

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/954,494	CASTILLO, JAMES G.
	Examiner Vickie Kim	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 recites the limitation "said volatile penetration enhancing agent" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Clarification required.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sipos(US 5,993,836) in view of Castillo(US 5,993,836).

The claims read on a method of applying local anesthetics in lipophilic base in lower alcohols to provide local anesthesia.

Sipos teaches a topical anesthetic composition and a method of obtaining an enhancement of its anesthetic activity by combining the anesthetic agent(e.g. lidocaine,

prilocaine, or mixture thereof) with an effective amount of a penetrant accelerator(i.e. cyclohexyl substituted alkanols) in vehicles including lower alcohols (e.g. ethanol , isopropanol); see abstract and claims 1-25, especially column 9, lines 26-27 and examples 7-11. Sipos teaches C5-17 aliphatic alcohols as the said potentiator(e.g. phenyl alcohols); see columns 4-5. For instance, example 9 at column 15, teaches a topical anesthetic gel composition comprising 50% ethanol, 4% anesthetic agent, and 12% penetrant accelerator(i.e.cyclohexyl alkanols), 5% carbosil, and so on.

Applicant's claims differ because they use and include specific terms "lipophilic base", "homogeneous solution", "volatile solvent", "cool sensation", "evaporation", etc.

However it would have been obvious to one of ordinary skill in the art to modify Sipos into claimed composition because the deficiencies in Sipos are commonly known to any artisan having ordinary skill in the art wherein they are equivalently substitutable due to inherent features, well known techniques, common knowledge, etc.

In any events, Castillo supports this examiner's allegation by teaching about a topical local anesthetic treatment comprising the steps of incorporating eutectic mixture of lidocaine and prilocaine within a lipophilic base(C 8-18 aliphatic alcohols) to provide rapid-onset, stability and optimal absorption; see abstract and claim 10. It further teaches suitable additives such as thickeners, thinner, stabilizers, surfactants, etc.

Thus One would have been motivated to make the local anesthetic containing composition comprising lidocaine or eutectic mixture of lidocaine+prilocaine, incorporated within lipophilic base, mix into volatile solvent(i.e. ethanol, isopropanol) to maximize therapeutic efficacy with optimal dosage, delivery including penetration as

evidenced by Sipos; see test comparison with various vehicles; see table V at column 16-17.

All the minor variations required in dependent claims are properly included in this rejection because the minor variations including the selection of optimal dosages, routes of administration, or variable applications in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

### ***Conclusion***

All the pending claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,  
Patent examiner  
November 15, 2001

  
William Jarvis  
Primary examiner  
Art unit 1614